UNITED STATES DISTRICT COURT

for the

Western District of Virginia

United States of America
v.
Indivior Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc.) and Indivior PLC
Defendant

Case No. 1:19cr00016

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS IN A CRIMINAL CASE

To: Food and Drug Administration, Office of the General Counsel, Food and Drug Division, 10903 New Hampshire Ave., Building 31, Silver Spring, MD 20993

(Name of person to whom this subpoena is directed)

YOU ARE COMMANDED to produce at the time, date, and place set forth below the following books, papers, documents, data, or other objects:

See Attachment A.

Place:	Date and Time:
Jones Day 51 Louisiana Ave., N.W. Washington, D.C. 20001-2113	12/30/2019 10:00 am

Certain provisions of Fed. R. Crim. P. 17 are attached, including Rule 17(c)(2), relating to your ability to file a motion to quash or modify the subpoena; Rule 17(d) and (e), which govern service of subpoenas; and Rule 17(g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

(SEAL)

Date: _____

CLERK OF COURT

Signature of Clerk or Deputy Clerk

The name, address, e-mail, and telephone number of the attorney representing *(name of party)* Indivior Inc. and Indivior PLC, who requests this subpoena, are:

James Wooley, 901 Lakeside Ave E, Cleveland, OH 44114, jrwooley@jonesday.com, 216.586.7345;
Leigh Krahenbuhl, 77 West Wacker Dr, Suite 3500, Chicago, IL 60601, lkrahenbuhl@jonesday.com, 312.269.1524

Notice to those who use this form to request a subpoena

Before requesting and serving a subpoena pursuant to Fed. R. Crim. P. 17(c), the party seeking the subpoena is advised to consult the rules of practice of the court in which the criminal proceeding is pending to determine whether any local rules or orders establish requirements in connection with the issuance of such a subpoena. If no local rules or orders govern practice under Rule 17(c), counsel should ask the assigned judge whether the court regulates practice under Rule 17(c) to 1) require prior judicial approval for the issuance of the subpoena, either on notice or ex parte; 2) specify where the documents must be returned (e.g., to the court clerk, the chambers of the assigned judge, or counsel's office); and 3) require that counsel who receives produced documents provide them to opposing counsel absent a disclosure obligation under Fed. R. Crim. P. 16.

Please note that Rule 17(c) (attached) provides that a subpoena for the production of certain information about a victim may not be issued unless first approved by separate court order.

Case No. 1:19cr00016

PROOF OF SERVICE

This subpoena for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Criminal Procedure 17 (c), (d), (e), and (g) (Effective 12/1/08)

(c) Producing Documents and Objects.

(1) In General. A subpoena may order the witness to produce any books, papers, documents, data, or other objects the subpoena designates. The court may direct the witness to produce the designated items in court before trial or before they are to be offered in evidence. When the items arrive, the court may permit the parties and their attorneys to inspect all or part of them.

(2) Quashing or Modifying the Subpoena. On motion made promptly, the court may quash or modify the subpoena if compliance would be unreasonable or oppressive.

(3) Subpoena for Personal or Confidential Information About a Victim. After a complaint, indictment, or information is filed, a subpoena requiring the production of personal or confidential information about a victim may be served on a third party only by court order. Before entering the order and unless there are exceptional circumstances, the court must require giving notice to the victim so that the victim can move to quash or modify the subpoena or otherwise object.

(d) Service. A marshal, a deputy marshal, or any nonparty who is at least 18 years old may serve a subpoena. The server must deliver a copy of the subpoena to the witness and must tender to the witness one day's witness-attendance fee and the legal mileage allowance. The server need not tender the attendance fee or mileage allowance when the United States, a federal officer, or a federal agency has requested the subpoena.

(e) Place of Service.

(1) In the United States. A subpoena requiring a witness to attend a hearing or trial may be served at any place within the United States.

(2) In a Foreign Country. If the witness is in a foreign country, 28 U.S.C. § 1783 governs the subpoena's service.

(g) Contempt. The court (other than a magistrate judge) may hold in contempt a witness who, without adequate excuse, disobeys a subpoena issued by a federal court in that district. A magistrate judge may hold in contempt a witness who, without adequate excuse, disobeys a subpoena issued by that magistrate judge as provided in 28 U.S.C. § 636(e).

ATTACHMENT A

DEFINITIONS

1. "FDA" means the Food and Drug Administration and all its personnel, agents, attorneys, consultants, representatives, employees, officers, and directors.

2. "Related to" or "relating to" means directly or indirectly supporting, evidencing, describing, mentioning, referring to, referencing, contradicting, comprising or concerning.

3. "Records" means information stored either electronically or in physical form, including but not limited to documents; data; e-mails; faxes; tape recordings; affidavits; agreements; correspondence; memoranda; reports; notes; summaries; records of telephone conversations; interviews; and transcripts.

INSTRUCTIONS

1. The records requested herein shall be produced as they are kept in the usual course of business or shall be organized and labeled to correspond with each request to which they respond. The records are to be produced in full and unredacted form.

2. Reference to the singular in any of these requests shall also include a reference to the plural, and reference to the plural shall include a reference to the singular.

3. Use of the word "including" shall be construed to mean "without limitation."

4. "And" or "or" shall be construed conjunctively or disjunctively as necessary to make the requests inclusive rather than exclusive.

5. All responsive material should be produced which are known by, possessed or controlled by, or available to the FDA.

DOCUMENTS AND INFORMATION TO BE PRODUCED

1. The records reflecting the FDA Office of Prescription Drug Promotion's (formerly known as the Division of Drug Marketing, Advertising and Communications) receipt and review of the following promotional or marketing materials for Suboxone Film submitted by Reckitt Benckiser Pharmaceuticals Inc. ("RBPI") or Indivior Inc. between 2010 and 2019:

    a. Any submissions referencing Suboxone Film "Helping Address Public Health Needs;"

    b. Any submissions stating that Suboxone Film could "Help Address Misuse and Abuse";

c. Any submissions stating that Suboxone Film "Can Be Part of the Solution" to "misuse," "diversion and abuse," and "unintentional pediatric exposure";

d. Any submissions stating that "Nearly half of Suboxone Film prescribers surveyed cited 'potential for reduction of abuse and diversion' as a reason to prescribe vs Suboxone Tablet";

e. Any submissions including a chart with the heading, "Suboxone Film—Helping to Reduce the Risk of Pediatric Exposure";

f. Any submissions including a chart with the heading, "Suboxone . . . Film—associated with lower rates of diversion and abuse . . ."; and

g. Any submissions referencing data showing "fewer pediatric exposures for Suboxone Film vs Suboxone Tablet."

2. The records reflecting the FDA Office of Surveillance and Epidemiology review of Indivior's annual Risk Evaluation and Mitigation Strategy ("REMS") Assessment Reports submitted between 2009 and 2019 (including all such reports submitted by RBPI).

3. The annual assessment reports submitted between 2013 and 2019 by the Buprenorphine-containing Transmucosal products for Opioid Dependence ("BTOD") REMS group and related reviews by the FDA and its Office of Surveillance and Epidemiology.

4. The records reflecting the analysis and review underlying the conclusion reached by the FDA's Office of Surveillance and Epidemiology, as expressed and reviewed by Kellie Taylor and Gerald Dal Pan in connection with the office's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging" and that "the role of unit-dose packaging and child-resistant closures are well accepted measures of preventing accidental pediatric exposures to drug products." This will include all underlying data reviewed in assessing the comparative pediatric exposure risk.

5. The records reflecting the analysis and review underlying the conclusion reached by the FDA's Division of Anesthesia, Analgesia, and Addiction Products, as expressed and reviewed by Celia Winchell, Rigoberto Roca, and Bob Rappaport in connection with the division's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging." This will include all underlying data reviewed in assessing the comparative pediatric exposure risk.

6. The records reflecting the analysis and review underlying the conclusion reached by the FDA's Division of Medication Error Prevention and Analysis, as expressed and reviewed by Kellie Taylor, Sue Liu, and Carol Holquist in connection with the division's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that

"Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging." This will include any underlying data reviewed in assessing the comparative pediatric exposure risk.

7. The records reflecting the analysis and review underlying the conclusion reached by the FDA's Division of Epidemiology, as expressed and reviewed by Christian Hampp in connection with the division's assessment of the 2012 Reckitt Benckiser Pharmaceuticals Inc. Citizen Petition, that "Suboxone film in unit-dose packaging poses a lower overall risk of accidental pediatric exposure than Suboxone tablets in multi-dose packaging" and that "if there is a return to market dominance of buprenorphine/naloxone tablets without unit-of use packaging, pediatric exposures are likely to rise." This will include any underlying data reviewed in assessing the comparative pediatric exposure risk.

8. The records reflecting the guidance provided to generic buprenorphine manufacturers regarding the FDA's classification of the packaging of buprenorphine-containing products as a "significant safety issue in regards to pediatric exposure," including the FDA's recommendation to switch to unit-dose packaging for buprenorphine-containing products. This will include, but not be limited to, the documents reflecting the communications or analysis conducted in advance of and in connection with the guidance provided to generic buprenorphine manufacturers during the April 9, 2013 meeting of the Buprenorphine Product Manufacturers Group on the BTOD REMS Submission.

9. The meeting materials and minutes from meetings or calls of the Buprenorphine Product Manufacturers Group in 2013.

10. The records reflecting the FDA review or analysis of the dosage amounts included in the approved labels for the Suboxone Tablet and Suboxone Film.

11. The records reflecting the FDA analysis of Suboxone Film packaging that led to its March 29, 2010 letter to RBPI.

12. The records reflecting the support and basis for the FDA's policy, finalized in February 2019, "to encourage widespread innovation and development of new buprenorphine treatments for opioid use disorder."

13. The records relating to the congressional testimony of FDA Commissioner Scott Gottlieb in October 2017 and any other FDA personnel regarding the expanded utilization of buprenorphine treatments.

14. The records reflecting the review and analyses of RiskMap reports submitted by RBPI/Indivior to the FDA related to the Suboxone Tablet, including but not limited to the analyses of unintended pediatric exposure, misuse and abuse, and physician and patient understanding of risks of misuse and abuse.